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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/784,980	02/16/2001	Anthony John Bell	5641C1-07-LAV	5253

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PFIZER, INC.
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EXAMINER

MADSEN, ROBERT A

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/784,980

Applicant(s)

BELL ET AL.

Examiner

Robert Madsen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 and 46-54 is/are pending in the application.
- 4a) Of the above claim(s) 10-27 and 46-54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 28-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

1. The Response filed January 20, 2005 has been entered. Claims 1-36 and 46-54 remain pending in the application. Claims 10-27 and 46-54 were withdrawn from consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1, 4-9, 28, and 31-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Carpenter et al. (US 5637344).

5. See the Office Action mailed September 20, 2004.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1, 2, 4-9, 28, 29, 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsuragi et al. (EP 0732064 A1).

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9. Katsuragi et al. teach adding Ginkgo biloba to lozenges, or hard-boiled candies, and providing a bitterness-relieving agent to suppress the unpleasant mouthfeel associated with a botanical, such as Ginkgo biloba, as recited in claims 1,2,28,29. Katsuragi et al. teach the bitterness-relieving agent comprises an ester of a mono/diglyceride with a carboxylic acid or salt, which may be further dissolved in palm kernel oil for delivery as recited in claims 1,4,5,28,31,32. Katsuragi et al. teach the bitterness relieving agent, or ester, is effective to suppress the unpleasant mouthfeel of the botanical at 0.01-10% of total composition. However Katsuragi et al. fail to explicitly teach the quantity of oil that is effective to suppress the unpleasant mouthfeel as recited in claims 1,6-9,28,33-36 (See Abstract, Page 3, lines 9-13, Page 3, line 58 to Page 4, line 5, Page 4, lines 25-47, Examples 3 and 4, Claims).
10. Oravainen et al. teach adding oil to hard candy will prevent sticking during formation of the candy and make the product more opaque. In one example, Oravainen et al. teach adding 1% oil (Abstract, Page 7, lines 15-25, Example 3)
11. Therefore, it would have been obvious to dissolve the ester in oil prior to addition to the hard candy of Katsuragi et al. since Katsuragi et al. teach dissolving the ester in oil prior to using and Oravainen et al. teach it is advantageous to include oil in a hard candy composition to prevent sticking and provide opacity. By dissolving the ester in the oil, the resulting oil becomes effective to suppress the unpleasant mouthfeel. To select any particular level of the effective oil, such that the level is 0.5-5% , 0.5-3.5% ,or 0.75 to 3.0% in the hard candy as recited in claims 1,6,7,28,33,34 would have been obvious depending on (1) the amount of botanical included , (2) the particular amount of

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ester required to suppress the unpleasant mouth feel of the botanical, and (3) the amount of oil required to dissolve the ester, since Katsuragi et al. teach 0.01-10% ester, based on the hard candy composition, is needed to suppress the unpleasant mouthfeel of a botanical and the ester is dissolved in the oil prior to adding to the hard candy composition. Additionally, to select any particular ratio of oil to botanical ratio such as 1.0/0.6 to 1.0.15 as recited in claims 8,9,35,36 would have been obvious depending (1) the amount of ester required to suppress the bitterness and (2) the amount of oil required to dissolve the ester prior to the addition to the hard candy composition since Katsuragi et al. teach 0.01-10% ester in the hard candy composition will be effective at suppressing the unpleasant mouth feel and the ester may be dissolved in oil prior to using.

12. Claims 3 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katsuragi et al. (EP 0732064 A1) as applied to claims 1, 2,4-9,28,29,31-36 above, in view of Raymont (AU 9671904 A).

13. Katsuragi et al. teach Ginkgo biloba added to lozenges/troches, but are silent in teaching a hard candy with Echinacea. Raymont is relied on as evidence of the conventionality of adding ginkgo biloba and Echinacea to lozenges/troches. Raymont teaches the combination of active ingredients has a significant synergistic effect such that the therapeutic effect is greater than a merely additive effect. In particular, Raymont teach Echinacea provides immune system benefits(Page 2, lines 7-12, Page 3, lines 10-31, Page 5, line 22). Therefore, it would have been obvious to further

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include Echinacea, depending on the desired benefit of the troches, since Raymont teaches combining both Ginkgo and Echinacea in a medication will have a synergistic effect, and Echinacea, in particular will improve the immune system.

Response to Arguments

14. Applicant's arguments, filed January 20, 2005 with respect to Sheu have been fully considered and are persuasive since the hard boiled candy portion of Sheu does not contain the fat coated fiber. The rejection of claims 1, 4-7 under 35 U.S.C. 102(b) as being anticipated by Sheu et al. (US 4698232) has been withdrawn.

15. Applicant's arguments filed January 20, 2005 with respect to Katsuragi et al. have been fully considered and are persuasive since Katsuragi et al. do not explicitly state "a bitterness relieving agent comprising an ester of a mono/diglyceride with a carboxylic acid or salt and an oil" and that the 0.01-10% weight bitterness relieving agent refers to the weight of an ester and oil in the medicinal composition. Thus, the rejection of claims 1, 2, 4-9, 28, 29, 31-36 under 35 U.S.C. 102(b) as being clearly anticipated by Katsuragi et al. (EP 07332064 A1) and Claims 3 and 30 under 35 U.S.C. 103(a) as being unpatentable over Katsuragi et al. (EP 0732064 A1) in view of Raymont (AU 9671904 A) have been withdrawn. However, upon further consideration, a new ground(s) of rejection is made as set forth above.

16. Applicant's arguments filed January 20, 2005 have been fully considered, but are not persuasive with respect to Carpenter et al. Applicant's contend that because Carpenter et al. teach the cocoa powder is less than 15 microns in size with generally

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round edges, the cocoa powder does not have rough texture and does not have an unpleasant mouthfeel. Carpenter et al. teach milling cocoa powder to avoid unacceptable texture of cocoa containing hard candies in an effort to match the texture of conventional hard candies, and Carpenter et al. teach that the texture of a candy comprising milled cocoa powder is an improvement over a candy comprising unmilled cocoa powder (Column 1, lines 25-49). However, Carpenter et al. teach mixing oil with the milled cocoa powder in order to improve the texture of the final product (Column 6, lines 58-65). Therefore, because Carpenter et al. seek to match the texture of conventional hard candies and Carpenter et al. teach adding oil to the milled cocoa powder to *improve* the texture of the final product, Carpenter et al. do suggest there is still some degree of an unpleasant mouthfeel or texture associated with the milled cocoa, relative to the texture of conventional hard candies, which can be suppressed or improved by adding oil to the composition.


Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Madsen whose telephone number is (571) 272-1402. The examiner can normally be reached on 7:00AM-3:30PM M-F.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert Madsen
Examiner
Art Unit 1761

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